K111945

AUG - 5 2011

510(K) SUMMARY: IMPAX Next Generation

Common/Classification Name: Picture Archiving and Communications System 21CFR 892.2050
Proprietary Name: IMPAX Next Generation
Agfa HealthCare N.V.
Septestraat 27
B-2640 Mortsel
Belgium
Contact: Jodi Coleman, Prepared: June 8, 2011
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A. LEGALLY MARKETED PREDICATE DEVICES

This is a 510(k) for Agfa's IMPAX Next Generation, which is a picture archiving and communications system. It is substantially equivalent to Agfa's IMPAX workstations with MPR, Digital Subtraction and 3D (K022292), and for orthopedic use to its Agfa Orthopedic Software for IMPAX Workstations (K071972), and for mammography to Agfa's IMPAX MA3000 (K081976).

B. DEVICE DESCRIPTION

The new device is largely similar to the predicate devices. It is a comprehensive PACS system that combines the features of IMPAX system with the mammography workstation. This new version includes improvements to the user interface and is designed for ease of deployment and service. It also includes an integrated patient information system, report generation and dictation and transcription features.

Principles of operation and technological characteristics of the new and predicate devices are the same. There is no change to the intended use of the device vs. the predicate devices.

C. INTENDED USE

IMPAX Next Generation is a Picture Archiving and Communications System (PACS). It provides an interface for the acquisition, display, digital processing, annotation, review, printing, storage and distribution of multimodality medical images, reports and demographic information for diagnostic purposes within the system and across computer networks. IMPAX Next Generation is intended to be used by trained healthcare professionals including, but not limited to physicians, radiologists, orthopaedic surgeons, cardiologists, mammographers, technologists, and clinicians for diagnosis and treatment planning using DICOM compliant medical images and other healthcare data.

MPR, MIP and 3D rendering functionality allows the user to view image data from perspectives different from that in which it was acquired. Other digital image processing functionality such as multi-scale window leveling and image registration can be used to enhance image viewing.

As a comprehensive imaging suite, IMPAX Next Generation integrates with servers, archives, Radiology Information Systems (RIS), Hospital Information Systems (HIS), reporting and 3rd party applications for customer specific workflows.

Lossy compressed mammography images and digitized film images should not be used for primary image interpretation. Uncompressed or non-lossy compressed "for presentation" images may be used for diagnosis or screening on monitors that are FDA-cleared for mammographic use.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

Agfa's IMPAX Next Generation has an Indications for Use statement largely similar to the statements for the predicate devices (K022292, K071972 and K081976). The statements have been combined and simplified. Intended uses are the same. The devices have the same technological characteristics. Descriptive characteristics and performance data are adequate to ensure equivalence.

Differences in devices do not alter the intended therapeutic/diagnostic effect.

PRODUCT COMPARISON TABLE				
	IMPAX Next Generation (NEW DEVICE)	**IMPAX General PREDICATE (K022292)**	**IMPAX Orthopedic PREDICATE (K071972)**	**IMPAX Mammography PREDICATE (K081976)**
Communications	DICOM	DICOM	DICOM	DICOM
Orthopedic Use, Treatment planning	√		√	
Mammographic Use	√			√
Operating system	Windows Vista	Windows 2000	Windows 7	Windows 7
Network Access	√	√	√	√
Multiple displays	√	√	√	√
Image Export	BMP, JPG, TIF, AVI	BMP, JPG, TIF, AVI	BMP, JPG, TIF, AVI	BMP, JPG, TIF, AVI
Window Level	√	√	√	√
Multi-Scale Window Level	√			
Pan/Zoom	√	√	√	√
Rotate	√	√	√	√
Calibrate/Measure	√	√	√	√
Annotate	√	√	√	√
MIP, MPR	√	√		
Musica Image Reprocessing	√			
3D Rendering	√	√		
Patient Information System (HIS/RIS)	√			
Dictation & Speech Recognition	√			

Table 1: Device Predicate Comparison

E. TECHNOLOGICAL CHARACTERISTICS

Agfa's IMPAX Next Generation is a PACS device for the acquisition, display, digital processing, annotation, review, printing, storage and distribution of multimodality medical images, reports and demographic information for diagnostic and treatment planning purposes.

It is a software device running on commercially available computer equipment that allows users to view and modify DICOM compliant medical images and patient information.

F. TESTING

The new device includes proven technology from the Agfa predicates which has been tested to demonstrate its suitability for digital mammography.

The device has been designed and manufactured to conform to the following standards:

- ACR/NEMA PS3.1 – 3.18 Digital Imaging and Communications in Medicine (DICOM)
- ISO 14971 Application of Risk Management to Medical Devices
- ISO 13485 Medical Devices - Quality Management Systems - Requirements For Regulatory purposes

IMPAX Next Generation has been tested and shown to conform to documented requirements. Validation testing confirms that usability, measurements, image processing and image quality meet user expectations.

No clinical trials were performed in the development of the device.

G. CONCLUSIONS

This 510(k) has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Agfa HealthCare N.V.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

AUG - 5 2011

Re: K111945
Trade/Device Name: IMPAX Next Generation
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: July 7, 2011
Received: July 8, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Mary S Pastel

Mary S. Pastel, Sc.D.
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111945

Device Name: IMPAX Next Generation

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Prescription Use ___X___		Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)	AND/OR	(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Mary S Pastel

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety
510(k) K111945